

6 QUALITY ASSURANCE

A. General Description

Quality assurance and improvement is a continuous monitoring and evaluation process designed to ensure that all services provided through the Montana Breast and Cervical Health Program (MBCHP) meet acceptable standards of professional practice and accountability.

The specific goals of quality assurance are to:

Goal 1—ensure that clinical services are valid and of high quality.

Goal 2—ensure that test results are interpreted and reported in a timely and accurate manner.

To achieve these quality assurance goals, the MBCHP will:

- implement policies and systematic procedures designed to monitor and improve the MBCHP program.
- identify corrective actions to be taken to remedy any problems found in the quality of care provided to the MBCHP's target population.

The specific policies and procedures to be followed and practices to be monitored are described in Part B below.

B. Policies and Procedures

1. Enrolled Medical Service Provider Qualifications / Certification Policies

- a. Clinical breast exams, bimanual pelvic exams, and Pap tests may be performed by a physician (medical doctor or doctor of osteopathy), naturopathic physician, physician assistant, certified nurse midwife, and/or certified nurse practitioner, provided the professional maintains a valid license to practice in Montana. □♦❖
- b. Mammography facilities must be fully certified by the Food and Drug Administration under the Mammography Quality Standards Act of 1992 (MQSA). □❖
- c. Cytology facilities must be fully certified by the Food and Drug Administration under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). □❖

2. Procedures for Reporting to the MBCHP

- a. Mammography providers must use the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS), 3rd edition, for mammography examination, interpretation, and results (see Appendix G-1). ❖

- b. Staging results of breast cancers must be reported using clinical stage diagnosis according to the American Joint Committee on Cancer Staging (see Appendix G-2). ❖
- c. Cytology providers must report Pap test results using the Bethesda 2001 System (see Appendix G-4). ❖
- d. Staging results of cervical cancers must be reported using clinical stage diagnosis according to the American College of Obstetrics and Gynecology (see Appendix G-6). ❖
- e. Administrative sites must assist in the MBCHP evaluation process by distributing client and provider assessments as needed. ◆
- f. Enrolled medical service providers must submit all required client data collection forms¹.

3. Procedures for Informing Clients of Test Results

- a. Enrolled medical service providers must notify each MBCHP client by letter, telephone conversation, or office visit about the results of any test or procedure performed for the client. Notification should be confidential (see Part 6, “Client Confidentiality Procedures,” later in this chapter) and delivered within 10 working days of receiving results. The notification should include an explanation of results in terms that can be easily understood by the client. ❖
- b. In all cases, enrolled medical service providers must document in each client’s medical file² the date they mailed notification to or spoke with the client to inform her of results, and the method of notification (see Chapter 4, Part D-7 “Clients Considered Lost to Follow-up”). ❖
- c. Within 10 working days of receiving abnormal results, enrolled medical service providers must communicate the results to MBCHP clients by telephone conversation, office visit, or letter.
- d. Before considering a client “lost to follow-up,” providers, administrative sites, and/or contract partner sites must make three attempts to notify the client within 6 weeks of receiving the abnormal results. The third and final notice should be sent by certified mail with return receipt requested (see Chapter 4, Part D, “Tracking and Follow-up”). ❖◆

¹ See Appendix B for a definition of data collection forms.

² In this manual, the term “medical file” refers to records kept in the enrolled medical service provider’s office. The term “client record” refers to the MBCHP data collection forms and other supporting documentation.

4. Abnormal Test Results Requiring Follow-up

To ensure the follow-up of abnormal test results and the subsequent diagnosis of “cancer” or “not cancer,” enrolled medical service providers must clearly indicate “Diagnostic Work-up Planned” when marking breast and cervical screening data collection forms (see Appendix Q) with a result listed below:

- a. Cervical screening results ❖
 - ASC-H (Atypical Squamous Cells: Cannot Exclude High-Grade SIL)
 - AGC (Atypical Glandular Cells and adenocarcinoma)
 - HSIL (High grade Squamous Intraepithelial Lesions)
 - Squamous Cell Cancer
- b. Clinical breast exam results ❖
 - Abnormal, Suspicious for Cancer
- c. Mammography test results ❖
 - BI-RAD Category 4—Suspicious Abnormality
 - BI-RAD Category 5—Highly Suggestive of Malignancy
 - BI-RAD Category 0—Assessment Incomplete

5. Abnormal Screening Results: Time Standards for Tracking and Follow-up

The MBCHP will monitor screening data for adherence to the following standards of timeliness for tracking and follow-up. These standards are also used by the Centers for Disease Control and Prevention (CDC) to evaluate overall program quality:

- a. Abnormal screening Pap test result ❖
 - presentation for screening test to date of final diagnosis < 60 calendar days
 - date of final diagnosis to date treatment initiated < 60 calendar days
- b. Abnormal screening mammogram and/or clinical breast exam test result ❖
 - presentation for screening test to date of final diagnosis < 60 calendar days
 - date of final diagnosis to date treatment initiated < 60 calendar days

6. Client Confidentiality Procedures

Client confidentiality must be maintained in accordance with the Uniform Health Care Information Act and the Health Insurance Portability and Accountability Act (HIPAA) and with the following requirements:

- a. Have all clients sign the MBCHP “Informed Consent and Authorization to Disclose Health Care Information” form (see Appendix Q) confirming their consent to the release of medical information—for the purpose of data collection and reporting—between physicians, administrative sites, and the Montana Department of Health and Human Services (MDPHHS). Please note that the “Informed Consent and Authorization to Disclose Health Care Information” form permits exchange of information for 6 months only, starting on the date the client signed the form. ♦❖

- b. Fax MBCHP data collection forms to the MDPHHS at **1-877-764-7575 or 406-444-7465** if local to the Helena area. If unable to fax the MBCHP data collection forms, mail them in a secure envelope clearly marked “Confidential.” ♦❖
- c. Exercise caution and discretion if client information is to be discussed over the phone. ♦❖
- d. Notify a client of test results either by telephone, office visit, or mail. Do not use any means of communication that cannot ensure confidentiality. Do not send test results to the client by postcard or fax, and do not leave results in a message on an answering machine or with another person. ❖
- e. Have volunteers sign a statement of confidentiality agreeing to keep all MBCHP information confidential. ♦
- f. Provide a client with copies of her MBCHP records only upon receiving a written request from her. This request must include her signature. To ensure the confidentiality of client information, do not provide copies of records solely upon an oral request. □♦❖

7. Compliance with Guidelines for Age of Population Served

MBCHP will regularly review client screening data to monitor compliance with MBCHP eligibility guidelines, which require that a minimum of 75 percent of all mammograms paid for by MBCHP must be for women who are 50 years of age or older. □

8. Compliance with Guidelines for Cervical Policy

- a. MBCHP will regularly review client screening data to monitor compliance with MBCHP cervical policy. (See Chapter 4, Part D-4, “Additional Requirements for Cervical Screening.”) (See Appendix P.)
- b. MBCHP will regularly review client screening data to monitor compliance with MBCHP eligibility guidelines for women who have had a hysterectomy. (See Chapter 4, B-3, “Additional Eligibility Guidelines for Women Who Have Had a Hysterectomy.”)
- c. MBCHP will regularly review client screening data to monitor compliance with MBCHP reimbursement policy for liquid based cervical cytology. (See Chapter 4-7, part e)